IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEMS PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL 2327
ETHICON WAVE 6 CASES LISTED IN EXHIBIT A OF DEFENSE NOTICE OF ADOPTION	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE

PLAINTIFFS' MEMORANDUM IN OPPOSITION TO DEFENDANTS' MOTION TO EXCLUDE CERTAIN GENERAL OPINIONS OF BRUCE ROSENZWEIG, M.D.

The Plaintiffs respectfully request that this Court deny Defendants' motion that seeks to exclude certain opinions of Dr. Bruce Rosenzweig's general TVT-Secur opinions for the Wave 6 cases.

INTRODUCTION

Dr. Rosenzweig is Plaintiffs' expert in urogynecology. See curriculum vitae of Dr. Rosenzweig attached hereto as Exhibit "A". Dr. Rosenzweig is a board-certified gynecologist specializing in urogynecology and an assistant professor of obstetrics and gynecology at Rush University Medical Center in Chicago, Illinois. *See* wave 6 expert report of Dr. Rosenzweig attached hereto as Exhibit "B". Dr. Rosenzweig has performed over a thousand pelvic floor surgical procedures on women with stress urinary incontinence and pelvic organ prolapse. *Id.* He has also performed over 250 surgeries to address complications related to synthetic mesh devices like that at issue here. *Id.*

In his Wave 6 expert report, Dr. Rosenzweig offers opinions regarding, *inter alia*, the design defects of the TVT Secur device. Ethicon's attacks on Dr. Rosenzweig's general opinions are, for the most part, adoptions of prior wave briefings, with the exception of two new

arguments it makes concerning Dr. Rozensweig's TVT-Secur opinions. As to the arguments previously raised in Defendants' Wave 5 briefing, Plaintiffs' similarly adopt their briefing from the prior wave cases. With respect to the two new arguments raised by Defendants in their current Wave 6 briefing (Doc. No. 4880), those arguments – which are erroneous at best and misleading at worst - should be rejected outright, as set forth in greater detail below. Contrary to Defendants' suggestions, Dr. Rosenzweig's opinion are reliable and supported by a sound methodology, including his review of numerous peer-reviewed medical and scientific publications and Defendants' own internal corporate documents. Indeed, these same general opinions have already been admitted in three different trials in Pennsylvania state courts, which Defendants wholly fail to mention in their 4-page wave 6 brief. *Engleman v. Ethicon, Inc., et al.*, March Term 2014, No. 5384; *Adkins v. Ethicon, Inc., et al.* July Term 2013, No. 00919; and *Ebaugh et al. v. Ethicon, Inc., et al.*, July Term 2013, No. 00866.

LEGAL STANDARDS

Federal Rule of Evidence 702 sets forth the basic framework for analyzing the admissibility of expert opinions.

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

Fed. R. Evid. 702.

If the witness is suitably qualified, then the *Daubert* inquiry generally breaks down into a two-step analysis. The first issue is whether the proffered evidence represents "scientific knowledge," meaning that it is supported by appropriate validation. The second issue is whether the evidence would assist the jury. *United States v. Dorsey*, 45 F.3d 809, 813 (4th Cir. 1995).

This aspect of the inquiry is often discussed in terms of whether the expert's opinions "fit" the case. *See Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 591-92 (1993).

ARGUMENT

I. The Court should deny Ethicon's motion to exclude Dr. Rosenzweig's reliable opinions that the TVT Secur's fleece tips and implanting introducer were defectively designed – opinions supported by numerous peer-reviewed journal articles and Defendants' own internal company documents, contrary to the erroneous and misleading arguments made by Defendants.

Defendants' Wave 6 briefing only directly addresses opinions offered by Dr. Rosenzweig concerning two of his several design defect opinions associated with TVT Secur device. Specifically, that: 1) the fleece tips and 2) the implanting introducer were both defectively designed. Def. Brief (Doc. No. 4880) at 2. In support of their arguments to exclude these opinions, Defendants erroneously misstate and/or misrepresent the scope of and basis for Dr. Rosenzweig's opinions. Contrary to Defendants' arguments, Dr. Rosenzweig clearly demonstrated that he used reliable methods in rendering his opinions about these two design defects which are supported by the numerous peer-reviewed publications and Defendants' own internal company documents, which Dr. Rosenzweig cited to in his Wave 6 expert report and during his sworn discovery and trial testimony.

A. Dr. Rosenzweig's design defect opinions about TVT Secur's fleece tips are reliable as demonstrated by the numerous medical/scientific articles and internal company documents referenced by Dr. Rosenzweig in his expert report and in sworn deposition and trial testimony.

Defendants' erroneously argue that Dr. Rosenzweig "cites no support whatsoever for his suggestion that the ETHISORB fleece tips contributed to fixation problems" and that his opinion in this regard "has not been subject to peer-review or testing, and he cites no studies related to this issue." Def. Bf. (Doc. No. 4880) at p. 2. However, Dr. Rosenzweig cited numerous

publications and internal documents in his expert report and during sworn discovery and trial testimony demonstrating the reliability of this opinion.

Dr. Rosenzweig opines in his Wave 6 expert report that one of the several design defects of the TVT Secur was the fleece tips that Defendants added to the ends of the modified sling device which provided inadequate fixation which lead to an unreasonably high failure rate and recurrent stress urinary incontinence compared to women treated with Defendants' predicate sling devices. *See id*. at p. 4. This very opinion has been admitted in three separate trials which Defendants suspiciously fail to mention in their brief. *Engleman v. Ethicon, Inc., et al.*, March Term 2014, No. 5384; *Adkins v. Ethicon, Inc., et al.* July Term 2013, No. 00919; and *Ebaugh et al. v. Ethicon, Inc., et al.*, July Term 2013, No. 00866.

Despite Defendants argument to the contrary, Dr. Rosenzweig cited numerous peer-reviewed articles and Ethicon's own internal company documents to support this opinion. See e.g., *id*. at pp. 47, 63-65. In these few pages alone, Dr. Rosenzweig cited to at least 15 publications and internal company documents supporting his fleece-tip/high failure rate opinions, including systematic reviews of randomized controlled trials (level 1 evidence). *See. Id.* at p. 65 (citing Nambiar A, Single-incision sling operations for urinary incontinence in women; *Cochrane Database of Systematic Reviews* 2014, Issue 6. and Mostafa A, Single-Incision Mini-Slings Versus Standard Midurethral Slings in Surgical Management of Female Stress Urinary Incontinence: An Updated Systematic Review and Meta-analysis of Effectiveness and Complications; *European Urology*, 2014; 402-427).

During the *Engleman* trial, Dr. Rosenzweig went through many of the same studies and internal documents referenced in his expert report and reliance list and explained how each of the

sources supported his opinion that the TVT Secur fleece tips were defectively designed. For example, Dr. Rosenzweig testified:

> Q. Now, briefly tell us how this informs your opinions in this case.
>
> A. They found that at one year, 50 percent of women had failed.
> Q. What do you mean by "failed"?
>
> A. Meaning the device did not work to treat their stress urinary incontinence. They were still leaking urine when they cough or sneeze.
>
> Q. Does this article further support your opinions regarding the defective nature of the TVT Secur device?
>
> A. Yes. What they conclude is that the anchoring system, the fleece ends of the mesh, did not hold, and, therefore, the device failed.

See *Engleman v. Ethicon*, 4/13/2017 Trial Transcript (afternoon session) at 27:2-15 attached as Exhibit "C" (Dr. Rosenzweig citing the Krofta article which found a 50% failure rate to support his opinion that the TVT Secur fleece tips were defectively designed).[1]

Based on his review of the medical and scientific literature and Defendants' own internal company documents, Dr. Rosenzweig testified "[o]ne of the defects of the device is that the fleece tips don't hold. If the fleece tips don't hold, the mesh moves and migrates. If it moves and migrates, it's not there to hold up the middle portion of the urethra. The harm is that women will then leak urine again and will need another surgery to fix that leakage"). *Id*. at 38:11-39:11.

In a more recent *de bene esse* deposition – which lasted 4-days – Dr. Rosenzweig testified that "[t]he fleece tips were shown by the literature not to hold, which allowed the mesh to move and migrate, which decreased the efficacy of the procedure and increased the harm, such as erosion and pain." *Ebaugh v. Ethicon, Inc. et al.*, De Bene Esse Deposition of Dr. Rosenzweig (Vol. I), 7/14/2017 at 241:18-242:4 attached hereto as Exhibit "D". He went on to

[1] *See also id* at 26:7-27:15; 27:2-15; 28:5-29:23; 32:4-16; 42:6-43:4; 72:18-23; 112:22-113:6

identify three of the primary publications that directly address and support his opinion about the fleece tips, including Hota (2012), Hamer (2012) and Krofta (2012):

> Q. And, Doctor, before we were interrupted, can you just identify the medical publications that support your opinion concerning the fleece tips?
>
> A. Yes. There's a study by Hota from 2012, a study by Hamer from 2012 and a study by Krofta from 2012 that discuss the fleece tips not holding and increasing the -- or being responsible for failures to treat stress urinary incontinence and pain with intercourse.

Ebaugh v. Ethicon, Inc. et al., De Bene Esse Deposition of Dr. Rosenzweig (Vol. II), 7/15/17 at 583:13-21, attached hereto as Exhibit "E".

Thus, it is incorrect to suggest that "Dr. Rosenzweig cites no support whatsoever for his suggestion that ETHISORB fleece tips contribute to fixation problems" or that "[h]is opinion has not been subject to peer review or testing." On the contrary, the record is clear that Dr. Rosenzweig has spent considerable time identifying the publications and internal documents that support his design defect fleece tip opinions – a method this Court has routinely found to be reliable under *Daubert*. See e.g., *In Re: Ethicon Inc. Pelvic Repair Systems Product Liability Litigation, MDL No. 2327, Doc. No. 2668* (Aug. 26, 2016) at p. 7-8 (denying Defendants' challenge to Dr. Rosenzweig's alternative design opinions based on medical and scientific publications).

B. Dr. Rosenzweig's design defect opinions about TVT Secur's sharp arrowhead introducer are reliable as demonstrated by the numerous medical/scientific articles and internal company documents referenced by Dr. Rosenzweig in his expert report and in sworn deposition and trial testimony.

Defendants final argument is that Dr. Rosenzweig's opinions about the device's introducer should be excluded because, according to Defendants, Dr. Rosenzweig "notes only a 'possibility' that merely has been theorized and not subject to any testing or studies." Def. Brf at p. 3. Here again, Defendants argument is misleading and fails to acknowledge that Dr.

Rosenzweig's general opinions concerning the defective introducer have been admitted in every trial he has testified. *Engleman v. Ethicon, Inc., et al.*, March Term 2014, No. 5384; *Adkins v. Ethicon, Inc., et al.* July Term 2013, No. 00919; and *Ebaugh et al. v. Ethicon, Inc., et al.*, July Term 2013, No. 00866.

As an initial matter, Dr. Rosenzweig offered his opinion to a reasonable degree of medical certainty and those opinions are based on his knowledge, training and experience, his review of the published medical and scientific literature and review of Defendants' own internal documents. See Wave 6 Expert Report attached as Exhibit "B". In his expert report, Dr. Rosenzweig opinions that:

> For a number of reasons, the TVT-S was poorly designed and was a defective product/medical device. For instance, the TVT-S is more prone to failing and not maintaining the angle of correction at the urethra for control of stress incontinence because the length of the tape and the mechanism of insertion were different from the TVT and TVT-O. The TVT-S also had inadequate fixation and lack of support within the first 12 weeks because of the use of Ethisorb, tape length, and the release mechanism that were all known to affect the anchoring of the TVT-S. Such problems were known to Ethicon and also explained the inferior cure rates Ethicon saw with the TVT-S as compared to its predicate devices.

Id. at p. 4. He expounded on this more during his discovery deposition, testifying that:

> the introducer is of a design that increases the risk of injury, the introducer being the arrow shape of the introducer, and that the introducer has a difficulty of getting into the right position and into the right location and removal; that upon dislodging the introducer you can or removing the introducer you can dislodge the sling, which will decrease its ability to lead to stress urinary incontinence.
>
> The Ethisorb fleece end, Ethisorb, E-t-h-i-s-o-r-b, fleece end does not allow for fixation to adequately allow, quote-unquote, tissue integration, therefore increasing the chances of recurrence of stress urinary incontinence. The size of the introducer is large for the description of the incision size, which therefore leads to a dragging of either periurethral or perivaginal tissue, which leads to tissue disruption and also tissue damage which will lead to pain and dyspareunia. The depth of the incision needs to be deeper so that the mesh will lay flat and be able to be introduced in a way that decreases tissue disruption and tissue irritation and the mesh to lay flat to decrease complications.

Deposition of Bruce Rosenzweig, MD, 2/4/2016 at 115:15-23, attached as Exhibit "F".

Dr. Rosenzweig based his opinion about the TVT Secur device on several studies, including, but not limited to, a study by Hota et al.[2] In the Hota article, the researchers compared the TVT-O device to the TVT-S device and found a 19% erosion rate in the TVT-S arm compared to a 0% erosion rate in the TVT-S arm of the study. Other than the use of the same Prolene material, the TVT-S device differed from the TVT-O device in that the TVT-S was shorter, had fleece tips that were supposed to help fixate the device in the tissue and had a sharp, arrowhead introducer connected to the fleece tips which was used to cut through the vaginal tissue during the implantation procedure.

The authors of the Hota article wrote that "there also was an increased incidence of mesh exposure in the TVT-S group. Although the etiology of this complication is unclear, we theorize that the sharper edges of the TVT-S introducer potentially creates more trauma to the vaginal epithelium and may result in higher erosion rates." Defendants use the language from the Hota article to suggest Dr. Rosenzweig's opinions are unreliable by incorrectly suggesting that the Hota publication is based on an untested theory and that Dr. Rosenzweig only relied on this one study to support his opinions concerning the defects to the sharp, arrowhead introducer. However, this was just one of several studies that Dr. Rosenzweig relied on to support his opinions concerning the introducer. *Id*. at 157:21-22.

Moreover, when questioned further about the Hota study and the author's description of their theory, Dr. Dr. Rosenzweig explained:

> Q. And if you were to rank levels of evidence using the scientific method, how would you rank hypothesis, theory, testing and conclusion?
>
> A. Well, you start with the hypothesis, you test it and then you draw a conclusion.

[2] Hota L., "TVT Secur (Hammock) Versus TVT-Obturator," Female Pelvic Med. Reconstr. Surgery, 18(1):41-45 (2012), attached to Defendants Brief as Ex. I).

Q. Would you agree that theory would need to be subsequently proven in randomized controlled trials?

A. Well, this is a randomized control trial, and they felt that the sharp edges associated with the Secur was what they attributed their high erosion rate to.

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Q. And these authors indicate towards the bottom of Page 43, "The lower overall success of TVT Secur could be attributed to the difficulty that sometimes was encountered in the detachment of the introducer from the sling. During the introducer removal process, the original tensioning may have been compromised as the introducer was moved back and forth in an attempt to release the sling from the introducer."

Did I read that correctly?

A. Yes.

Q. So, is it your understanding that you would attribute the failure rate in this study to surgeon technique?

A. Right. No, I deal with that in my report. That is a design defect of the TVT Secur, difficulty in removing, releasing the Ethisorb fleece end and detaching and removing the introducer.

Id. at 159:21-161:21. Dr. Rosenzweig reliably explains that the "theory" was proven in this (and other) randomized controlled trials, including studies published by Lim[3] and Hinoul[4] which he also relies.

Furthermore, Dr. Rosenzweig identified numerous internal company documents that support his opinions that the sharp, arrowhead introducer is defects. In one internal memorandum, Dan Smith – the inventor of the TVT Secur – reports on a meeting he had with Prof. Nilsson – a Key Opinion Leader for Ethicon and a co-author of many of the full length TVT Retropubic publications wherein Dr. Nilsson reiterates his position that the sharp,

[3] *Ebaugh v. Ethicon, Inc. et al.*, De Bene Esse Deposition of Dr. Rosenzweig (Vol. II), 7/15/17 at 593:1-23, attached as Exhibit E (testifying that the Lim article supports his opinion that the TVT-S is defective, "namely, the sharp arrow tip introducer, the short, stiff, rigid mesh that are – lead to complications and therefore are unreasonably unsafe. They found a 20% groin pain and tape erosion rate of close to 8%.) *See also* id. at 595:19-597:15

[4] Id. at 602:3-24

arrowhead introducer is defective. *Engleman v. Ethicon Inc., et al.*, Trial Transcript 4/13/17 (afternoon session) at 32:17-33:23, attached as Exhibit "C". Another internal company document relied upon by Dr. Rosenzweig showed that "67 percent of doctors felt that the inserter was too sharp, that the arrowhead inserter was too sharp." *Id*. at 35:5-16. Dr. Rosenzweig testified that this design defect made the TVT Secur "an unreasonably unsafe device." *Id*. at 37:15.

Conclusion

Contrary to the Defendants claims, Dr. Rosenzweig used a reliable method in rending his opinions concerning his fleece tip and introducer defects. Unfortunately, it appears that Defendants overlooked key testimony and references made in his expert report and reliance materials resulting in their erroneous and misleading arguments. Because Dr. Rosenzweig's opinions are reliable, Defendants motion should be denied.

Dated: November 6, 2017

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on November 6, 2017, I electronically filed the foregoing document with the Clerk of the court using CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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